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FIRST NAMED APPLICANT

ATTORNEY DOCKET NO.

EXAMINER

ART UNIT

PAPER NUMBER

14

DATE MAILED

09/11/2001

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

THE PERIOD FOR RESPONSE:

a) is extended to run _____ or continues to run _____ from the date of the final rejection
b) expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

Appellant's Brief is due in accordance with 37 CFR 1.192(a).

Applicant's response to the final rejection, filed _____ has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:

- There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
- They raise new issues that would require further consideration and/or search. (See Note).
- They raise the issue of new matter. (See Note).
- They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

2. Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. Upon the filing an appeal, the proposed amendment will be entered will not be entered and the status of the claims will be as follows:

Claims allowed: None

Claims objected to: None

Claims rejected: 1, 5-10

However:

Applicant's response has overcome the following rejection(s): None

4. The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because See attached.

5. The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

The proposed drawing correction has has not been approved by the examiner.

Other

Art Unit: 1645

Response to Arguments

1. Applicant's arguments filed April 6, 2001 have been fully considered but they are not persuasive.
2. Applicant argues the rejection of Claims 1, 5-10 under 35 U.S.C. 102(b) as being anticipated or in the alternative under 35 U.S.C. 103 as obvious over Catt et al WO 95/13531 by asserting: the Catt et al apparatus is associated with a number of problems. The problem is defined by the statement: "One particular example of this problem is where the assay device is inserted into the slot, tip pointing downwards, so as to depress the actuator before the interlock has engaged the cooperating recess (709) provided on the assay device."
3. This argument has been considered, but is not convincing because the apparatus/device of the prior art is structurally the same as the invention now claimed, and what is argued is directed to operator error, rather than distinguishing the claimed invention from that of the prior art based upon structural and functional differences.
4. The instantly claimed invention is asserted to overcome possible operator error and will only provide a reading of the assay result when the assay device has been correctly positioned to provide a lock and key engagement specifically between the actuating means and *a portion of the assay device*.

Art Unit: 1645

5. It is the position of the examiner that the prior art discloses an apparatus that includes an actuating means that is triggered by the insertion of the assay device, and upon correct insertion, the actuating means causes the reading of the detection zone to be initiated (claim 13, page 34, lines 29-33). The "a portion of the assay device" argued by Applicant is not clearly defined in the claims. What is this portion that distinguishes the claimed invention from the prior art? The portion referred to appears to be the apparatus of the prior art. What switch or other means being argued, but not claimed, is not present in the prior art apparatus?

The prior art apparatus in figures 4a-4b, 5, 6 and 7 shows various structural features that define a lock and key relationship between the apparatus and the test strip inserted. The relationship of the test strip and the reading device is one in which the spacial relationship is interlocking to insure that a predetermined spacial relationship relative to said reading means is maintained (see page 23, lines 30-35). When the device is received into the reading device the receiving means includes an actuating means which is triggered (claim 13) by the receipt of the device and the actuating means causing the reading of the detection zone to be initiated.

The switch actuating means is taught to comprise a fixed projecting portion and a displaceable projecting portion. The casing also comprises a recessed contact portion to accommodate the fixed projecting portion of the switch actuating means.

Thus the reading is enabled only by contact and displacement action of test strip with the reading device. The asserted structural and functional novelty of enabling reading of the test strip after contact and displacement is accomplished by the device of Catt.

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6. Applicant argues the rejection of claims 1, 5-10 under 35 U.S.C. 103(a) as being unpatentable over Jina et al (US Pat. 5,526,120, filing date September 8, 1994) by asserting:

a. Jina absolutely fails to disclose or suggest the mechanical interaction specifically defined by Applicants claims.

There
b. ~~That~~ is no requirement for displacement of the interacting displaceable portion of the switch actuating mean be required to initiate reading.

7. Applicant's arguments filed with respect to Jina have been fully considered but they are not persuasive because:

Jina et al show a test strip with an asymmetrical end which insures the correct insertion for measuring ~~for~~ an analyte in a liquid sample. The test strip when fully inserted closes an electrical circuit, the closing of which is monitored by the apparatus and allows the determination of an analyte.

The closed electrical circuit is a type of switch actuating means that is completed only upon correct receipt of the assay device. (see col. 4, lines 47-67 and col. 5, lines 1-48; abstract and figures 7 and 8). Thus the reading is enabled only by contact and interaction of the test strip with the reading device. The test strip is displaceable, but when in a lock and key relationship, the circuit is completed, switch actuation achieved and assay results read. The asserted structural and functional novelty of enabling reading of the test strip after contact and displacement is accomplished by the device of Jina.

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With respect to formulation of the apparatus and test strip into kit form, the apparatus and test strip are taught to be used for medical measurement of blood analytes (see col. 1, lines 32-33 and col. 5, lines 34-35). Kits are known to provide means for commercialization, standardization and distribution of a product to the end user. The rejection of claims 1, 5-10 remain rejected for reasons of record in paper number 11, paragraphs 7-8.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.
Vgp
September 5, 2001

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